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## 510(K) SUMMARY

This summary of 5I0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 5I0(k) number is: K082811.

1. **Submitter's Identification:**

Qin Huajuan
**URIT Medical Electronic Co., Ltd.**
No. 4 East Alley, Jiuhua Road
Guilin, Guangxi, China 541001

Phone: 86 773 3112787
Fax: 86 773 2693847

Date Summary Prepared: August 17, 2009

2. **Name of the Device:**

Uritest-50 and Uritest-500B Urine Analyzers
Uritest 10G Urine Reagent Strips
Uritest 11G Urine Reagent Strips

3. **Common or Usual Name:**

Urine Chemistry Analyzer
Urinalysis Reagent Strips

4. **Classification Information:**

Division of Clinical Laboratory Devices
Panel: Clinical Chemistry (75)
Product codes: KQO, JIL, JIP
21 CFR Part 862.2900

5. **Predicate Device Information:**

Bayer Clinitek 500 Urine Chemistry Analyzer (K926359)
Bayer Multistix 10-SG Reagent Strips for Urinalysis (K052719)
Dirui URISTK H-11 Reagent Strips and Dirui H-500 Urine Analyzer (K040703)

6. **Device Description:**

The Uritest-50 and Uritest-500B Urine Analyzers are reflectance spectorphotometers that instrumentally measure the reflectance of a reacted Uritest 10G or Uritest 11G urine reagent strip for urinalysis.
The Uritest-50 and Uritest-500B Urine Analyzers display and print urinalysis results and can be connected to a laboratory computer for data management.

7. **Intended Use:**

The Uritest-50 and Uritest-500B urine analyzers are semi-automated, bench top instruments which are intended for prescription, in vitro diagnostic use only. The instruments perform semi-quantitative detection of the following analytes in urine: leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood, pH and ascorbic acid. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria. The instruments use the accompanying check strip for daily calibration.

Uritest 10G urine reagent strips provide semi-quantitative tests for leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood and pH in urine. The Uritest 10G urine reagent strips are for use with the Uritest-50 urine analyzer and are for prescription, in vitro diagnostic use only. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

Uritest 11G urine reagent strips provide semi-quantitative tests for leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood, pH and ascorbic acid in urine. The Uritest 11G urine reagent strips are for use with Uritest-500B urine analyzer and are for prescription, in vitro diagnostic use only. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

8. **Comparison to Predicate Devices:**

The Uritest-50 and Uritest-500B Urine Analyzers are reflectance spectrophotometers. It has similar technological characteristics to the CLINITEK 500 Urine Chemistry Analyzer and the Dirui H-500 Urine Analyzer. They are instruments which make it suitable for physician office laboratories. The user manually dips an Uritest 10G or Uritest 11G reagent strip into a urine specimen and places it on the Uritest-50 or Uritest-500B Urine Analyzer. The instrument times the reactions on the strip, measures the reflectance off the strip and converts the results to a clinically meaningful unit that corresponds to the color

chart on the bottle label of the strip. The urinalysis results are displayed on the instrument and can be printed or transferred to a laboratory computer.

9. **Performance studies**:

Studies were conducted in-house and in clinical settings to demonstrate that the performance of the Uritest-50 and Uritest-500B Urine Analyzers and Uritest 10G or Uritest 11G urine reagent strips are equivalent to the predicate devices.

10. **Conclusions:**

The results of in-house and clinical evaluations of the Uritest-50 and Uritest-500B Urine Analyzers and Uritest 10G or Uritest 11G urine reagent strips demonstrate that the device is equivalent in performance to the predicate devices and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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Urit Medical Electronic Co., Ltd.
c/o Ms. Maria Griffin
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: k082811
Trade/Device Name: Uritest-50 Urine Analyzer, Uritest-500B Urine Analyzer, Uritest 10G Urine Reagent Strips, Uritest 11G Urine Reagent Strips
Regulation Number: 21 CFR §864.6550
Regulation Name: Occult blood test
Regulatory Class: II
Product Code: JIO, JIL, CDM, JJB, JIN, JIR, JMT, LJX, CEN, JMA, KSL, KQO
Dated: September 9, 2009
Received: September 10, 2009

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

510(k) Number (if known): (k) 082811

Device Name: **Uritest-50 Urine Analyzer, Uritest-500B Urine Analyzer, Uritest 10G Urine Reagent Strips, Uritest 11G Urine Reagent Strips**

Indications for Use:

The Uritest-50 and Uritest-500B urine analyzers are semi-automated, bench top instruments which are intended for professional, in vitro diagnostic use only.

Depending on the reagent strips being used, the instruments perform semi-quantitative detection of the following analytes in urine: leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood, pH and ascorbic acid (Uritest 10G urine reagent strips don't have the ascorbic acid pad). Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria. The instruments use the accompanying check strip for daily calibration.

Uritest 10G urine reagent strips provide semi-quantitative tests for leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood and pH in urine. The Uritest 10G urine reagent strips are for use with the Uritest-50 urine analyzer and are for professional, in vitro diagnostic use only.

Uritest 11G urine reagent strips provide semi-quantitative tests for leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood, pH and ascorbic acid in urine. The Uritest 11G urine reagent strips are for use with Uritest-500B urine analyzer and are for professional, in vitro diagnostic use only.

Prescription Use ____✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Division Sign-Off Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) 082811